



DEC - 3 2004

Mr. Roland A. Poirier  
Co-Founder and President  
ImmunAct, Inc.  
P.O. Box 284  
Barton, Vermont 05822

Dear Mr. Poirier:

This is in response to your letter of November 26, 2004 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that ImmunAct, Inc. is making the following claims, among others, for the products **ImmunAct™ Lactobacillus Acidophilus & Rhamnosus** and **ImmunAct™ Boulardii Probiotic Blend**:

“[U]se as an adjunctive treatment for prevention and treatment of antibiotic-associated diarrhea”

“[G]enerally related to inhibition of pathogens....”

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for these products suggest that they are intended to treat, prevent, or mitigate a disease (i.e., antibiotic-induced diarrhea and infectious disease caused by pathogenic microorganisms). These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that these products are intended for use as drugs within the meaning of 21 U.S.C. 321(g)(1)(B), and that they are subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, Montrose Metro II, 11919 Rockville Pike, Rockville, Maryland 20852.

975-0163

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Please contact us if we may be of further assistance.

Sincerely yours,

*for Robert J. Moore*

Susan J. Walker, M.D.

Director

Division of Dietary Supplement Programs

Office of Nutritional Products, Labeling

and Dietary Supplements

Center for Food Safety

and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-310

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of  
Enforcement, HFC-200

FDA, New England District Office, Office of Compliance, HFR-NE240

November 26, 2004

Food and Drug Administration  
Center for Food Safety and Applied Nutrition  
Office of Nutritional Products, Labeling, and Dietary Supplements (HFS-810)  
5100 Paint Branch Parkway  
College Park, MD 20740

NOV 30 2004

Dear Sir or Madam:

Pursuant to Section 403(r)(6) of the Federal Food, Drug and Cosmetic Act and Section 101.93 of FDA's regulations, we hereby notify you that we are using the following statement(s):

(1) **Name and address of distributor:**

ImmunAct Inc., P.O. Box 284, Barton, VT 05822

(2) **Statements:**

"These friendly probiotics help to maintain a healthy digestive system"

- *Saccharomyces boulardii* (ATCC7412) is genetically identical to *Saccharomyces cerevisiae* CBS9526). *Saccharomyces boulardii* has a long history of use as an adjunctive treatment for prevention and treatment of antibiotic-associated diarrhea.
- *Bifobacterium Longum* Rosell0175. Recently identified as *B. lactis*, this microorganism is the most prominent strain that lines the large intestine and the last part of the small intestine, as well as in the vaginal tract. This organism is known for producing acetic and lactic acids, which lower the PH of its surroundings. *Bifidobacteria* have potential probiotic activity that is generally related to inhibition of pathogens, maintenance and restoration of normal intestinal flora.

(3) **Name of the dietary ingredient(s) if not provided in the text of the statement:**

Probiotic Bacteria 10 Billion Organisms

*L.acidophilus* Rosell0052, *L.rhamnosus* Rosell0011, *Bifidobacterium longum* Rosell0175,  
*Saccharomyces Boulardii* (ATCC74012)

(4) **Name of the dietary supplement(s):**

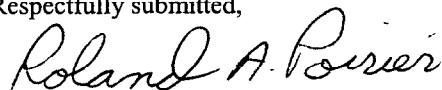
ImmunAct™ Boulardii Probiotic Blend

(5) **The following disclaimer appears on the label in bold:**

This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

I certify that the information contained in this notice is complete and accurate, and that ImmunAct Inc. has substantiation that the statement is truthful and not misleading.

Respectfully submitted,



Roland A. Poirier  
Co-Founder & President  
ImmunAct Inc.

90287

November 26, 2004

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Center for Food Safety and Applied Nutrition  
Office of Nutritional Products, Labeling, and Dietary Supplements (HFS-810)  
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